

Remarks

Objections

Drawings/37 C.F.R. §1.83(a)

The drawings have been objected to under 37 C.F.R. §1.83(a). The Office Action asserts that the drawings must show every feature of the invention specified in the claims and that the “lubricious substance” must be shown or the feature(s) canceled from the claim(s).

Applicants have amended Figs. 1 to show this feature. Reference is made to the lubricious substance in the description for Fig. 1 found on page 5, lines 10-15, throughout the specification and in the claims. No new matter has been added.

Rejections

35 U.S.C. §112

Claim 8 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action asserts that there is an inconsistency between the language of the preamble that recites ‘an elastomeric sleeve’ and certain portions in the body of the claim that recites, “a lubricious substance.”

Claim 8 has been amended and the preamble no longer recites “an elastomeric sleeve”. Applicants respectfully request withdrawal of the rejection of claim 8 under 35 U.S.C. §112.

35 U.S.C. §102(b)

Claim 8 has been rejected under 35 U.S.C. §102(e) as being anticipated by Konya et al. (US 6123723). The Office Action asserts that Konya et al. disclose elastomeric material for a sleeve for retaining a stent (col. 17, lines 22-26; Konya et al. also disclose fluid opening or “ports” in the sleeve to deliver a fluid material to aid in positioning the stent (col. 22, lines 57-61); and that the opening are fully capable of allowing a lubricious substance to pass through them.

Claim 8 has been amended such that it is directed to a stent delivery catheter including elastomeric sleeves that overlap only the proximal margin, only the distal margin, or only the proximal margin and the distal margin of the stent, but not the entire stent. Support for this amendment is found in the drawings.

Konya et al. do not disclose a sleeve which overlaps only the proximal margin, only the distal margin, or only the proximal margin and distal margin, but not the entire stent. Thus, Konya et al. do not disclose all of the elements of the claimed invention as required under 35 U.S.C. §102(b). Applicants respectfully request withdrawal of the rejection of claim 8 as being anticipated by Konya et al., US 6123723 under 35 U.S.C. §102(b).

Claims 1, 2 and 8 have been rejected under 35 U.S.C. §102(e) as being anticipated by Blaeser et al. (US 6168617). The Office action asserts that Fig. 2 shows a stent delivery system having a catheter 18 with a balloon 22 mounted thereon and that it can also be seen that there is a stent 48 on the catheter. The Office Action also asserts that Blaeser shows a sheath or sleeve 28 with an overlay portion that covers the stent; that the sheath has a cone portion and waist overlay portion at its end; that the sheath or sleeve also has at least one port 60; that the port is fully capable of allowing a lubricious substance to pass through it; and that with respect to claim 8, Blaeser discloses that a "lubricious" substance such as silicone is on the inside of the sleeve, col. 6, lines 1-3.

Applicants traverse the rejection.

Blaeser et al. disclose improved arrangements to secure and cover a stent on a delivery catheter to better facilitate delivery thereof. Blaeser et al. disclose at col. 4, lines 20-28 that the stent delivery system 10 further comprises stent securement means, such as a sheath, indicated generally at 26 in FIGS. 1-3, comprising a very flexible thin walled sleeve or sheath 28 having a proximal end 30, a distal end 32 (as shown specifically in FIGS. 2-6), an exterior surface 34 and an interior surface 36, and a distal elastomeric sock, cuff or collar 38 (shown in FIGS. 1-3), having a proximal end 40, a distal end 42, exterior surface 44 and an interior surface 46.

As can be seen from FIGS. 1-3, the proximal end 40 of sock, cuff or collar 38 overlaps the distal end 32 of sheath 28. See also claim 1.

Applicants submit that claims 1, 2 and 8 of the present application are not anticipated by Blaeser et al. because the structure as found in claims 1, 2 and 8 do not include a sheath which is overlapped by a sock, cuff or collar as described and claimed in Blaeser et al., rather, the apparatus as found in claims 1 and 2 of the present application include a sleeve without the additional sock, cuff or collar overlaying the sleeve, an apparatus which is thus seen as being more simplistic than that described by Blaeser et al.

Thus, the stent delivery device of the present invention is not the same as that disclosed and claimed by Blaeser et al. as required under 35 U.S.C. §102(b).

Based on the foregoing, Applicants respectfully request withdrawal of the rejection of claims 1,2 and 8 under 35 U.S.C. §102(b) as being anticipated by Blaeser et al., US 6168617.

35 U.S.C. §103(a)

In the Office Action, the Examiner rejected claims 1 and 2 under 35 USC §103 as being unpatentable over U.S. Patent No. 4,950,227 ("Savin") in view of Konya. Applicant respectfully traverses the §103 obviousness rejection. Applicant respectfully asserts that there is no lubricant application port in Savin, as required in claims 1 and 2. Nor is there any suggestion, teaching, or motivation in Savin to provide any type of lubricant port. Savin indicates that a "lubricating solution can be provided between balloon 14 and sleeve 18 and 20", but does not teach how the lubricating solution is provided. There is no teaching, suggestion, or motivation in Savin to apply lubrication through a port after the stent is mounted onto the balloon and placed under the sleeves 18 and 20.

Applicant respectfully asserts that it is essential to consider all elements of the claimed invention. (*Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir 1991) Also, the claimed invention must be considered as a whole. (*Jones, supra*). The fact that all the elements of the claimed invention were not previously disclosed, as a whole, in Savin, Konya, or a combination thereof, precludes proper rejection pursuant to 35 USC §103. It is legally improper to focus on the obviousness of substitutions and differences between the claimed invention and the prior art rather than on the obviousness of the claimed invention **as a whole** relative to that prior art

(Emphasis added). (*Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1383, 231 USPQ 81, 93 (Fed. Cir. 1986)). Applicant respectfully further submits that Konya teaches a port through which contrast solution may be provided. There is no teaching, suggestion, or motivation to provide lubrication between the sleeve and the stent. Without such a suggestion, teaching, or motivation, Applicant again respectfully asserts that obviousness cannot be established simply by combining the teachings of the prior art to allegedly produce the claimed invention using hindsight (*In re Fine*, 5 USPQ 2d, 1596 (1988) (Fed. Cir. 1989)).

In the Office Action, claims 1 and 2 were rejected where the Examiner stated that "it would have been obvious to one of ordinary skill in the art to use the ports as taught by Konya in the sleeves taught by Savin et al. to provide application routes to deliver lubrication for removal of the sleeves." However, there is no suggestion, teaching, or motivation, in either reference individually and/or in combination to provide a lubricious substance through a port to lubricate between the sleeve and stent after the stent was mounted on the balloon and placed under the sleeve(s). Savin discloses that "a lubricating solution can be provided between balloon 14 and sleeve 18 and 20 to aid in the release of stent 16 from the sleeves" (Column 4, 55-57). Applicant respectfully asserts that the rejection of claims 1 and 2 pursuant to 35 USC §103 impermissibly utilizes a hindsight "where that which only the inventor taught is used against its teacher." (*In re Dembiczak*, 50 U.S.P.Q.2d 1614 (CAFC 1999)). Furthermore, as argued above, there is no suggestion, reason, or motivation presented in either Konya or Savin, either explicitly or implicitly, for combining the two references. The Applicant respectfully submits that it is improper to merely substitute the lubricating solution of Savin with the port for providing contrast solution of Konya in attempting to establish the rejection in view of 35 USC §103. Without evidence of such a suggestion, teaching, or motivation, the Examiner is simply taking the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability, which is the essence of hindsight. (*Dembiczak, supra*) Applicant respectfully requests that the Examiner allow claims 1-2 in view of 35 USC §103.

As indicated in the background of the application (Col. 3 line 14-29) lubricious coatings are well known in the art. What was not well known in the art was

being able to lubricate between the sleeve and stent after the stent was mounted on the balloon and placed under the sleeve(s). The person of ordinary skill in the art, after reviewing both Savin and Konya, would coat the inside of the sleeve as part of the manufacturing process and use the contrast solution port to inject contrast solution—not use the port for a totally different purpose and in a totally different manner than taught in either reference.

Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1 and 2 pursuant to 35 USC §103(a).

Formalities

If an extension of time is required to make this response timely and no separate petition is enclosed, Applicant hereby petitions for an extension of time sufficient to make the response timely. In the event that this response requires the payment of government fees and payment is not enclosed, please charge Deposit Account No. 22-0350.

CONCLUSION

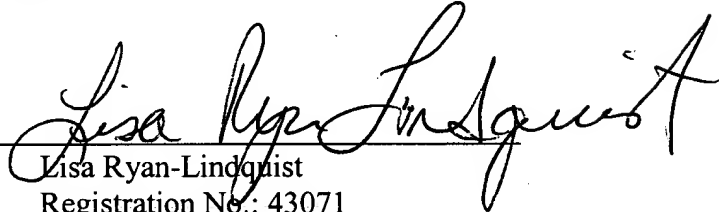
Claims 1, 2 and 8 are pending in the application. Applicants have addressed each of the issues present in the Office Action. Because it is believed that the amendment to claim 8 and the arguments advanced herein place claims 1-2 and 8 in condition for allowance, applicant respectfully requests that this amendment after final be entered. The Applicant respectfully requests consideration of the claims herein and that the rejections be withdrawn and the claims be allowed. Early action to that effect is earnestly solicited.

Respectfully submitted,

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